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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/403,940	01/12/2000	LUDWIG WILDT	990667/RSB	7875

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EXAMINER

GAKH, YELENA G

ART UNIT

PAPER NUMBER

1743

DATE MAILED: 03/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/403,940

Applicant(s)

WILDT ET AL.

Examiner

Yelena G. Gakh, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 January 2004.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-32 is/are pending in the application.
4a) Of the above claim(s) 23-28 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 18-22 and 28-32 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 29 October 1999 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____

DETAILED ACTION

1. Amendment and response filed on 01/15/04 are acknowledged. Claims 18-32 are pending in the Application. Claims 18-22 and 29-32 are elected with traverse. Claims 23-28 are withdrawn from consideration as drawn to the non-elected invention.

Response to Amendment

2. The objection to the Abstract and rejections of the pending claims under 35 U.S.C. 112, second paragraph, while slightly modified, remain. The rejections over the prior art are slightly modified in view of the amendment.

Specification

3. The Abstract of the specification is objected to on the same basis as claim 18 is rejected under 35 U.S.C. 112, second paragraph: it is not clear, how can "prestored values" be prepared. If they are already "prestored", they should not be prepared; if they have to be "pre-stored", they need to be prepared before they are pre-stored, and this step should be done before actual measurement. The language of the Abstract is confusing.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 18-21 and 29-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 recites "preparing prestored values" in step (d). As it was indicated above, such recitation is not very logical. If the data should be pre-stored for an individual, they have to be

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obtained and stored before actual measurements, not after. Otherwise, how can the measurements be compared with "pre-stored" data?

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. **Claims 18-20 and 22** are rejected under 35 U.S.C. 102(b) as being anticipated by Casparie et al. (US 5,069,220)

Casparie teach a method for monitoring lung functioning by measuring an end exhaled CO₂ in a certain volume by NDIR spectroscopy (col. 6, lines 1-6), comparing the value obtained with the predetermined value, e.g. of CO₂ in inhaled breath, and generating an alarm signal if the value falls beyond the predetermined limits. He discloses "precise control over the sampling period to assure the extraction of samples only during the end tidal region, without relying on the sensing of relatively large respiratory gas flows (col. 2, lines 1-6).

8. **Claims 18 and 32** are rejected under 35 U.S.C. 102(b) as being anticipated by Mick et al. (US 5,355,893).

Mick teaches a "vital signs monitor" and a method for performing "a plurality of resistive measurements of certain predetermined parameters of the exhaled gases and a plurality of optical absorption measurements of other predetermined parameters of the exhaled gases", measuring value of CO₂ in exhaled gases and using these data in "conventional oxygen therapy" (col. 2, lines 64-69). "The monitor will alarm when threshold levels are exceeded relating to (1) tidal volume (TV) (volume of exhaled gas), (2) respiration rate (RR), (3) minute volume (RR.times.TV), (4) approximate oxygen consumed per breath, (5) approximate end tidal carbon dioxide, and (6) combinations of the above" (col. 1, lines 39-44).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. **Claims 21 and 29-30** are rejected under 35 U.S.C. 103(a) as being unpatentable over Casparie in view of the prior art cited by the Applicants (PA) or Savadi et al. (Ind. J. Medic. Research).

Casparie does not teach applying his method of monitoring CO₂ in exhale breathe for predicting ovulation, which inherently comprises hormonal fluctuations.

PA or Savadi disclose a correlation between the CO₂ content in exhale breathe and ovulation, which makes it obvious for anyone of ordinary skill in the art to apply the method of

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Casparie for predicting ovulation (hormonal fluctuations) because of the clear correlation between this physiological process and CO₂ content, demonstrated by PA and Savadi.

13. **Claim 31** is rejected under 35 U.S.C. 103(a) as being unpatentable over Casparie in view of Goodman et al. (US 5,404,871).

Casparie does not specifically teach his method in application to monitoring pharmaceutical therapy.

Goodman teaches "apparatus and methods for delivering an amount of aerosolized medicine for inspiration by a patient in response to the occurrence of appropriate delivery point or points in the patient's detected breath flow. ... Changes in the patient's breath flow patterns during the course of an aerosolized medication inspiration therapy program may be detected and used to adjust the controlled amount of medication to be delivered in a given administration and/or to inform the patient of the patient's condition or change in condition. The device also may contain a library of administration protocols or operating parameters for different medications and a means for identifying from the canister the medicinal contents of the canister for customizing operation of the apparatus" (Abstract). Specifically, in the Background of the Invention Goodman indicates that using methods of monitoring results of pharmaceutical therapy by changes in lung capacity are well known in the art (col. 4, lines 34-51).

It would have been obvious for anyone of ordinary skill in the art to apply Casparie's method to monitoring pharmaceutical therapy, because Goodman indicates that the lung capacity, which is determined in Casparie's method by determining amount of CO₂ in the expiratory gas, can be used for monitoring pharmaceutical therapy.

Response to Arguments

14. Applicant's arguments filed 01/15/04 have been fully considered but they are not persuasive. Casparie teaches the method, which comprises all steps recited in claims 18-22 and 29, and therefore the method recited in these claims is anticipated by Casparie. While Casparie in fact does not teach his method for predicting ovulation, Savadi discloses direct correlation between amount of CO₂ in exhaled gas and ovulation, thus indicating predictability of ovulation on the basis of CO₂ measurements. It is not clear, why the fact that Savadi's work is of "a pure

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scientific nature” makes it non-obvious to use its results? Savadi unambiguously demonstrates the correlation mentioned above, which makes it obvious for anyone of ordinary skill in the art to use monitoring CO₂ in exhaled gas for predicting ovulation.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yelena G. Gakh, Ph.D. whose telephone number is (571) 272-1257. The examiner can normally be reached on 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Yelena G. Gakh
3/8/04

A handwritten signature in cursive script, appearing to read 'Yelena Gakh', written in black ink.